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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/606,969  | 06/25/2003  | Guohua Chen          | DURE-312            | 6463             |
| 31498   | 7590        | 03/18/2009           | EXAMINER            |                  |
| DURECT CORPORATION<br>THOMAS P. MCCrackEN<br>2 RESULTS WAY<br>CUPERTINO, CA 95014 |             |                      | SILVERMAN, ERIC E   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1618                |                  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |
|   |             |                      | 03/18/2009          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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|--|--|--|--|
| <p align="center"><b>Advisory Action</b><br/><b>Before the Filing of an Appeal Brief</b></p> | <p><b>Application No.</b><br/>10/606,969</p> | <p><b>Applicant(s)</b><br/>CHEN ET AL.</p> |  |
|  | <p><b>Examiner</b><br/>ERIC E. SILVERMAN</p> | <p><b>Art Unit</b><br/>1618</p>            |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 09 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: \_\_\_\_\_.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/Eric E Silverman/  
Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: 1. The rejection over 35 USC 112 2nd para., Applicant first argues that Applicant is entitled to be his own lexicographer, and that the definiteness of claim language must be determined in view of the specification. These comments are not germane, because the specification does not define or otherwise clarify the language at issue. Applicants also argue that the term "gel-like" is "obviously" the same as a gel, and that a skilled artisan would "clearly" understand what "gel-like" means. In response, what is "obvious" is that gel means gel, and gel-like means something else. As Applicants admit, the term gel-like means "like a gel". Something may be "like a gel" but not be a gel. "Clearly" the artisan would recognize that there is some difference between "gel" and "gel-like;" because this difference is not clear, the claims are indefinite.

2. The rejection under 35 U.S.C. 103(a) over US 6,130,200, which Applicants refer to as "Brodbeck2". Applicants argue that this reference is missing elements such as specific polymers and solvents, and that such are not inherently present in the prior art. In this Argument, Applicants either misunderstand or misrepresent the Office's position. The '200 patent does in fact teach the particular polymers and solvents, (lactic acid polymer taught in col 14, solvent such as benzyl benzoate, ethyl benzoate and mixtures taught in col. 13, polymer molecular weight taught in col. 14 and claim 15 - see 12/9/08 action pages 2-4 for complete discussion). The '200 patent suggests, but does not require, these components to be put together in the manner specified by instant claims. The rejection does not rely on inherency with regard to the ingredients of the composition. Where the rejection does rely on inherency is the purported effect of the composition - delivery over 7 days or less. As an initial matter, Applicants discussion of the law of inherency is not completely correct, because Applicants confuse the legal standard for inherency with the evidentiary burden for meeting that standard. The legal standard is, as Applicants state, that the inherent feature or result must necessarily flow from the prior art. However, the evidentiary burden is only a showing of reasonable support for this conclusion; proof beyond a doubt is not required. That is "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP 2112 (citing Ex parte Levy, 17 USPQ2d (Bd. Pat. App. & Inter. 1990)). Here, the Office's position is that because Brodbeck specifically teaches the polymers (with appropriate molecular weights) and solvents of the claims, and the physical form (gel depot) of the instant claims, Brodbeck's composition must have the same characteristics, such as release profiles as the claimed invention. This conclusion is further bolstered by the observation that Brodbeck is solving the same problem that the inventors solve (provide a depot composition without burst effects), and by recognition that "[p]roducts of identical chemical composition can not have mutually exclusive properties." In re Spada 15 USPQ2d 1655 (Fed. Cir. 1990). Although Applicants response confuses and repeatedly misstates the Office's position (the rejection never posits that the release profile, or any other feature of the claims "may" be present as Applicants state - it is not clear if Applicants misunderstand or deliberately misstate the Office's position), the record shows that the Office has explained why there is a reasonable basis to believe that the applied art meets the claimed release profile. Because "the PTO [has shown] a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." Id. 15 USPQ2d at 1658. Applicant has not met this burden, and so the arguments are unpersuasive.

3. The rejection under 35 USC 103(a) over US 6,130,200 in view of WO 02/38185. Applicants' argue that "the Office's proposal of ... modifying [the '200 patent] to provide [WO '185's] solid implants would render [the '200 patent's] implants inoperable. Applicants' conclude that this is strong evidence of non-obviousness. Here, once again, Applicants either misunderstand or misstate the Office's position. The Office has not proposed modifying the '200 patent to form a solid, but to use solvents from WO '185 instead of or in addition to those in the '200 patent. This substitution is supported by sound technical reasoning: the two implants are quite similar, use the same polymers, and functioning in similar ways (both are injectable depots). In each case, the solvents are washed away in situ to transform an injectable liquid into an implant. Thus, it follows that the solvents used in each are functional equivalents and it would be obvious to substitute one for the other. Applicants, unencumbered by any evidence or technical reasoning, posit that this combination would render the implant of ' the '200 patent unsuitable for its purpose. Applicants are wrong. Both the '200 patent and WO '185 teach injectable liquids that, upon administration, form drug delivery implants in situ. Because they both have the same purpose and the same manner of operation, it is non-sensical to conclude that combining them could make them unfit for their identical purposes. On the contrary, prime facie obviousness is supported by a finding that two items have the same function in the art and are both suitable for the same purpose, as the solvents of the '200 patent and WO'185 here. See In re Leshin 125 USPQ 146 (CCPA 1960) (selection of known plastic to make container of a type known to be made of plastics prior to the invention was obvious); See also Sinclair & Carroll Co. V. Interchemical Corp., 325 U.S. 327 at 335, 65 USPQ 297 at 301 (1945) ("selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle.")